AUG 2 0 2003

K031204

510(k) SUMMARY

J. Morita USA, Inc.'s
DENTAPORT ZX Dental Device

Name of Device and Name/Address of Sponsor

Trade or Proprietary Name:	DENTAPORT ZX
Common Name:	dental handpiece and root canal length measuring device
Classification Name:	AC-Powered Dental Handpiece and Root Apex Locator
Product Code :	EKX and LQY

J. Morita USA, Inc.
9 Mason
Irvine, California USA 92618
Telephone: 949-581-9600
Facsimile: 949-581-9688
Contact Person: Mr. Junichi Miyata, President
Date Prepared: June 25, 2002

Intended Use

The DENTAPORT ZX is a dental root canal measurement and treatment device that can measure the length of the root canal and enlarge the canal while monitoring the position of the file tip inside the canal.

Technological Characteristics and Substantial Equivalence

The DENTAPORT ZX is a low-voltage electric motor and root canal length measuring device. The DENTAPORT ZX covered by this submission is identical in every respect to the DENTA PORT device already authorized by the FDA under K#022147. The only difference is a change in the instructions for use regarding the sterilization of the device.

The new sterilization parameters have been properly validated and result in a sterility assurance level of at least 10^{-6}. Thus, the changes in sterilization parameters do not raise any new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2003

J. Morita USA, Incorporated
C/O Mr. Keith A. Barritt
1425 K Street, N.W.
Fish & Richardson P.C.
11th Floor
Washington, DC 20005

Re: K031204
Trade/Device Name: Dentaport ZX
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX, LQY
Dated: May 15, 2003
Received: May 30, 2003

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS MA,
Interim Director
Division of Anesthesiology, General, Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: DENTAPORT ZX

Indications for Use:

The DENTAPORT ZX is a dental root canal measurement and treatment device that can measure the length of the root canal and enlarge the canal while monitoring the position of the file tip inside the canal.

Kevin Mulvey Sr RSN

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031204

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)